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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,108	02/13/2007	Pradman Qasba	65431(47992)	9769

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,108	QASBA ET AL.	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/19/06*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

I. Claims 1-45 are pending.

Election/Restriction

II. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Invention 1 Claims 1-12 and 43-45, drawn to a specific targeted glycoconjugate comprising a specific bioactive agent and a specific targeting compound wherein the bioactive agent and targeting compound are joined by a specific modified saccharide compound.

Invention 2 Claims 13-29, drawn to a method for the treatment of a specific disease or disorder comprising, administering to a subject in need thereof an effective amount of a specific targeted glycoconjugate comprising a specific bioactive agent and a specific targeting compound wherein the bioactive agent and targeting compound are joined by a specific modified saccharide compound.

Invention 3 Claims 13-29, drawn to a method for the detection of a specific disease or disorder comprising, administering to a subject in need thereof an effective amount of a specific targeted glycoconjugate comprising a specific bioactive agent and a specific targeting compound wherein the bioactive agent and targeting compound are joined by a specific modified saccharide compound.

Invention 4 Claims 30-42, drawn to a method for synthesize a specific glycoconjugate comprising a specific bioactive agent and a specific targeting compound

wherein the bioactive agent and targeting compound are joined by a specific modified saccharide compound.

The inventions listed as Inventions 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-4 is a glycoconjugate comprising a bioactive agent and a targeting compound wherein the bioactive agent and targeting compound are joined by a specific modified saccharide compound. However, the US Pat No 5,608,060 (issued March 1997; PTO 892) teaches a targeted glycoconjugate comprising a targeting compound such as avidin/biotin-targeting moiety (e.g. antibody) conjugate (see col. 10, lines 64 through col. 11, col. 18, lines 17-63, in particular), a drug moiety such as therapeutic agent, toxin or radionuclide (see col. 4, line 17-20, col. 13-14, in particular) joined by a modified saccharide compound such as galactosyl-biotinyl-human BSA clearing agent where the galactosyl is derivatized to expose or incorporated galactose residue (see col. 19, line 20-67, in particular).

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-4 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

III. Accordingly, Inventions 1-4 are not so linked as to form a single general inventive concept and restriction is proper.

IV. This application contains claims directed to the following patentably distinct species of glycoconjugate comprising (A) a specific bioactive agent identifiable in claims 2, 16, and 42, for example, (B) a specific targeting compound identifiable in claims 3-7, 17-21, and 37-41, (C) a specific modified saccharide compound identifiable in claims 8, 22, and 36 for treating (D) patentably distinct diseases such as the ones recited in claim 27.

The species of glycoconjugate comprising distinct bioactive agent and distinct targeting compound via distinct modified saccharide for treating distinct diseases are independent or

distinct because claims to the different species recite the mutually exclusive characteristics. Therefore, they are patentably distinct.

Irrespective of whichever group the applicant may elect, if Groups I or IV is elected, the applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of glycoconjugate comprising (A) distinct bioactive agents such as the ones recited in claims 2, 16, and 42, (B) a specific targeting compound identifiable in claims 3-7, 17-21, and 37-41, and (C) a specific modified saccharide compound identifiable in claims 8, 22, and 36.

If Group II or III is elected, the applicant is further required under 35 U.S.C. 121 to elect a method of treating or detecting using a single disclosed species of glycoconjugate comprising (A) distinct bioactive agents such as the ones recited in claims 2, 16, and 42, (B) a specific targeting compound identifiable in claims 3-7, 17-21, and 37-41, (C) a specific modified saccharide compound identifiable in claims 8, 22, and 36 for treating or detecting (D) a patentably distinct diseases such as the ones recited in claim 27 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 13, 14, 15, 30, 31, 43 and 44 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product claim are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting

rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, PhD whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.

VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
March 14, 2008